Evidence-Based Treatment of Tobacco Dependence: New Developments

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Monthly Teleconference Series

Wisconsin Bureau of Mental Health and

Substance Abuse Services

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Learning Objectives

- Epidemiology of smoking and smoking-attributable morbidity and mortality
- Nicotine as an addictive drug
- Tobacco dependence as a chronic disease
- Evidence- based counseling and pharmacotherapy for patients motivated to quit
- Wisconsin Tobacco Quit Line

Disclaimer

I have received research support (but no consulting or speaking fees) from the following companies that market smoking cessation medications:

- SmithKline Beecham
- GlaxoSmithKline
- Elan Corporation, plc

"Smoking is a custom loathsome to the eye, hateful to the nose, harmful to the brain, dangerous to the lungs, and in the black, stinking fume thereof, nearest resembles the horrible Stygian smoke of the pit that is bottomless."

King James I
Counterblaste to Tobacco, 1604

Per Capita Cigarette Consumption

Prevalence of Smoking in U.S. Adults

Data Source: National Health Interview Survey

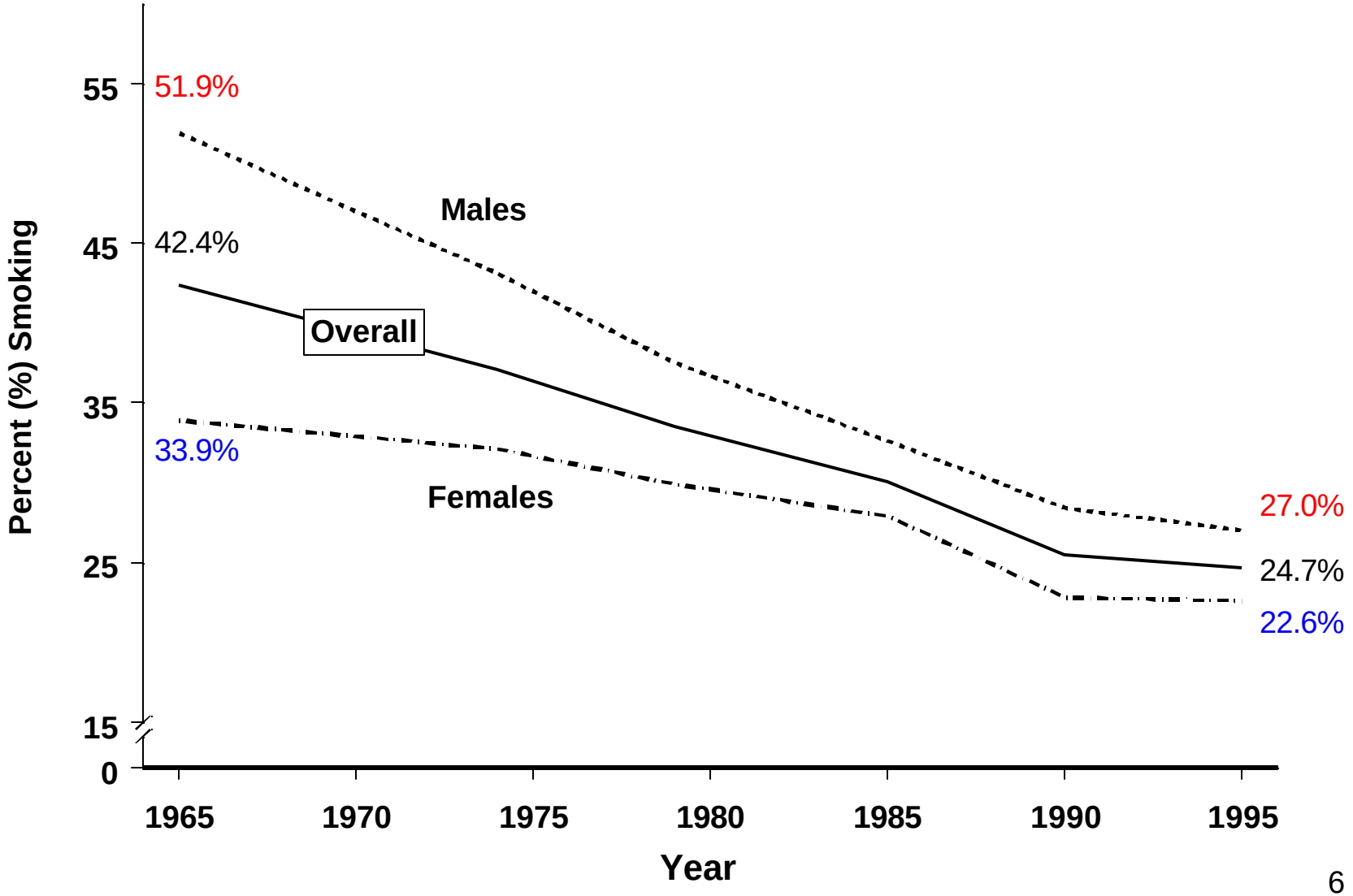
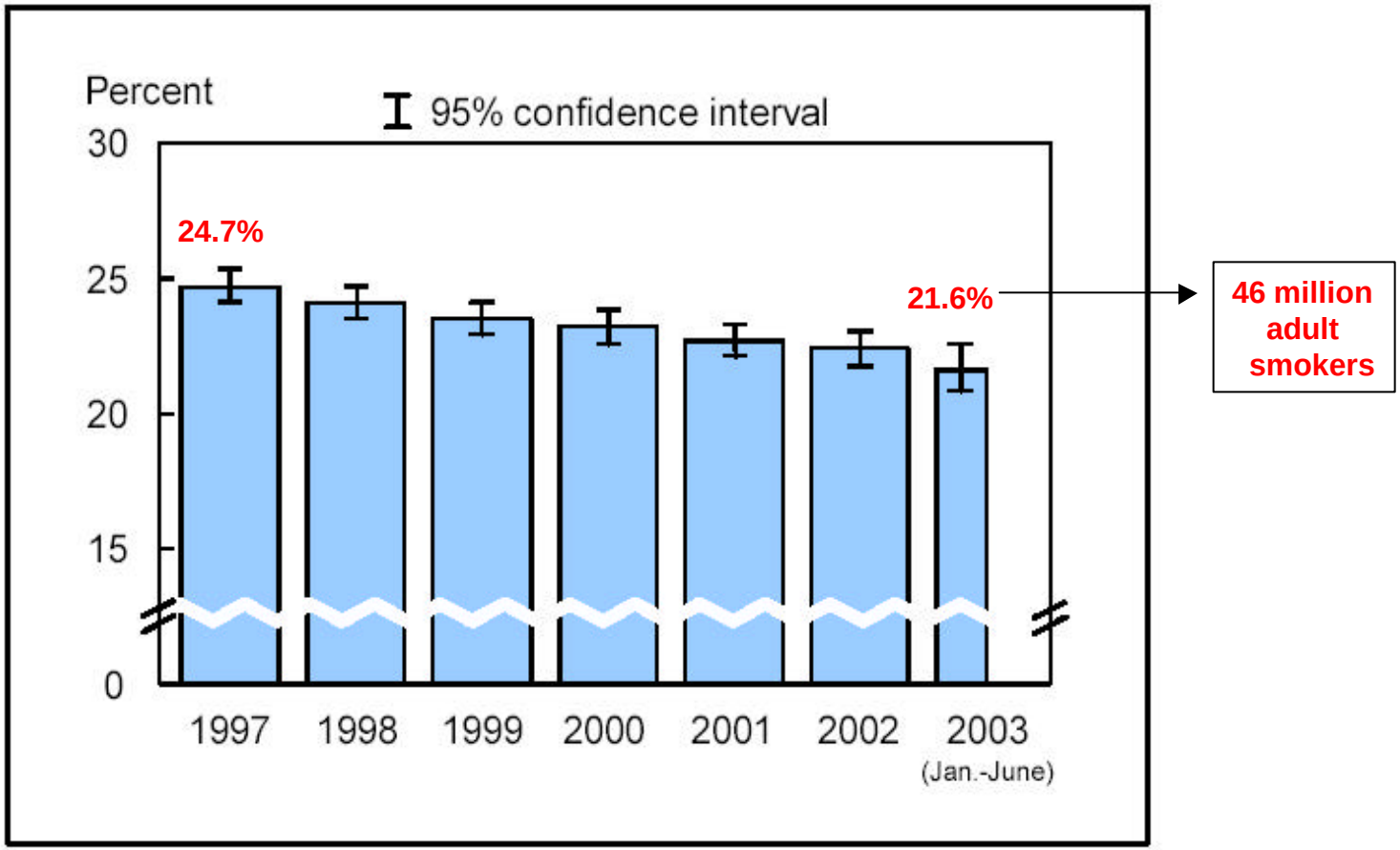
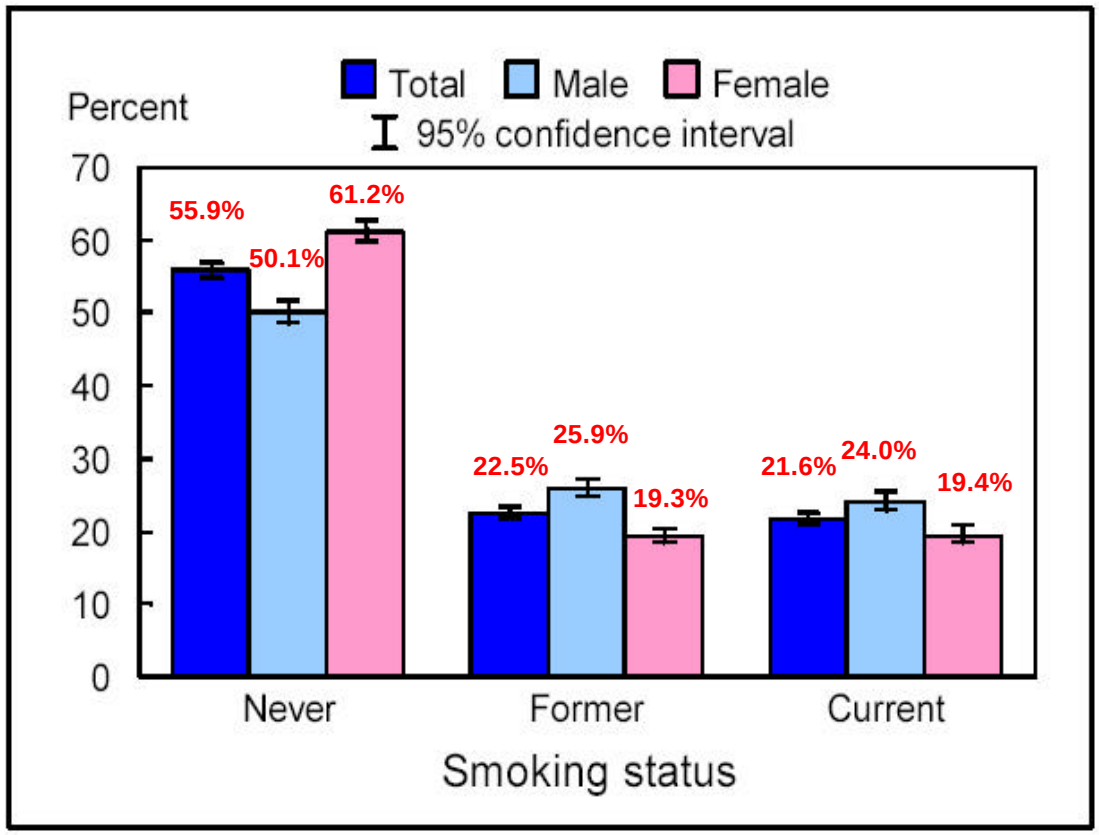


Figure 8.1. Prevalence of current smoking among adults aged 18 years and over: United States, 1997-2003



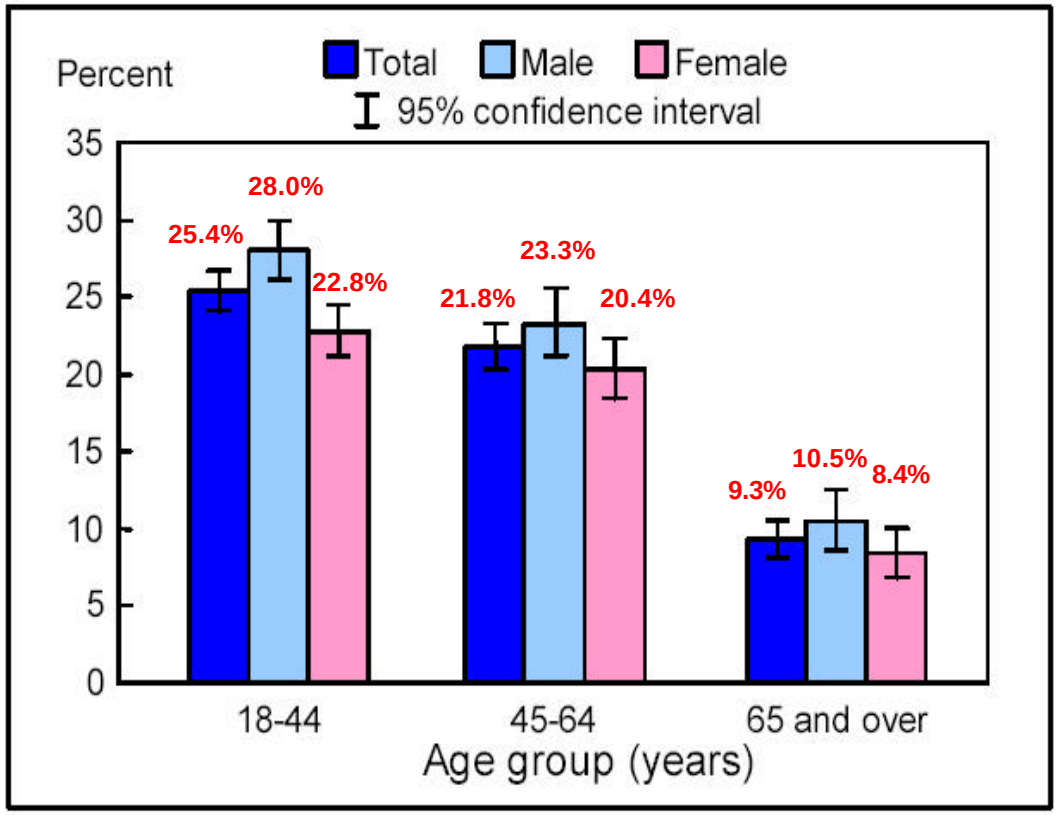
Data Source: Sample Adult Core component of the 1997-2003 National Health Interview Surveys. The estimate for 2003 was based on data collected January through June.

Figure 8.2. Percent distribution of smoking status among adults aged 18 years and over, by sex: United States, January-June 2003



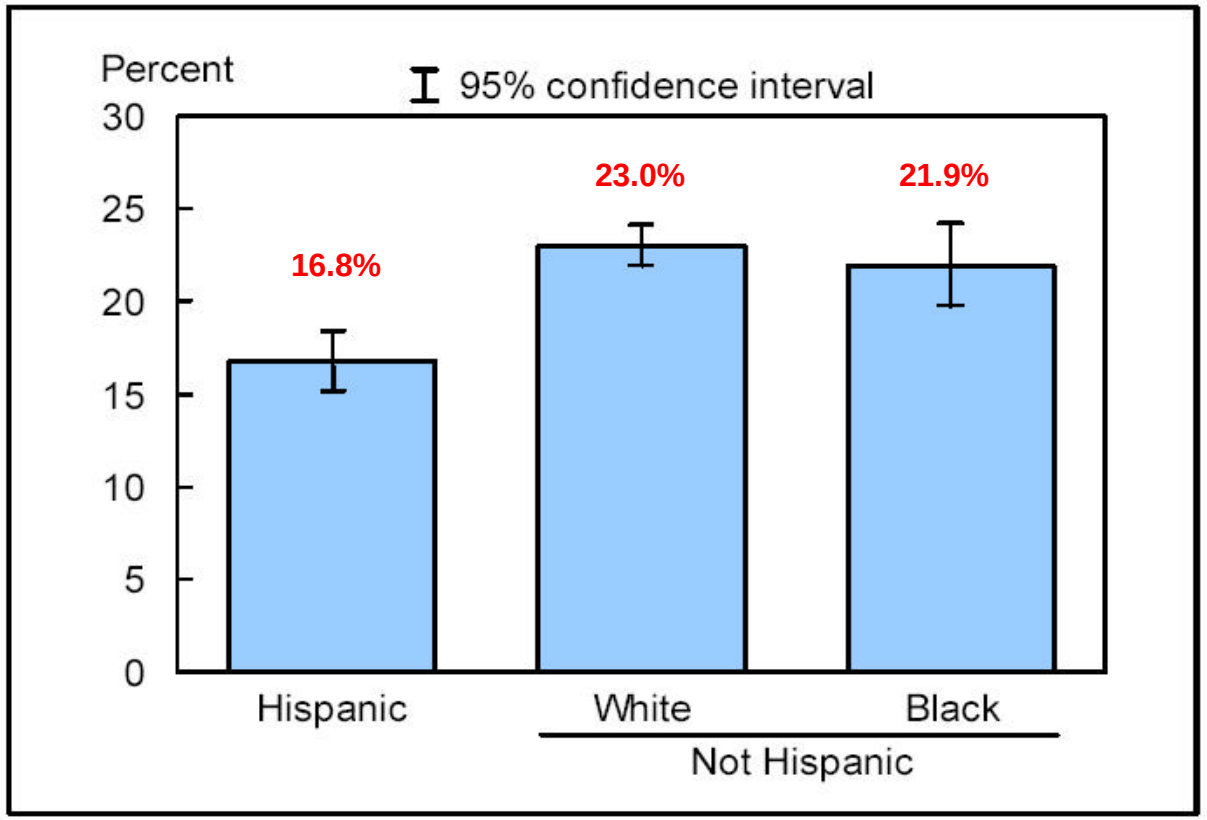
Data Source: Sample Adult Core component of the 1997-2003 National Health Interview Surveys. The estimate for 2003 was based on data collected January through June.

Figure 8.3. Prevalence of current smoking among adults aged 18 years and over, by age group and sex: United States, January-June 2003



Data Source: Sample Adult Core component of the 1997-2003 National Health Interview Surveys. The estimate for 2003 was based on data collected January through June.

Figure 8.4. Age- sex-adjusted prevalence of current smoking among adults aged 18 years and over, by race/ethnicity: United States, January-June 2003



Data Source: Sample Adult Core component of the 1997-2003 National Health Interview Surveys. The estimate for 2003 was based on data collected January through June.

Disproportionate Smoking Rates

The highest rates of smoking are seen in individuals :

- living below the poverty level
- with the least education
- working in blue-collar and service jobs
- with psychiatric and substance abuse disorders

Smoking Initiation and Course

- Most smokers become addicted as teenagers
- Every day more than 6000 adolescents try cigarettes for the first time
- More than half of the 6000 new “triers” will become daily smokers
- Addicted smokers will smoke, on average, for about 20-30 years or longer

Tobacco Advertising Spending vs. NIH Spending on Tobacco Research

Year	Total tobacco advertising and promotion*	NIH spending on tobacco research**
1990	$3.9 billion	<$110 million
1995	$4.9 billion	$126 million
2001	$11.2 billion	$414 million

*From *Federal Trade Commission Cigarette Report for 2001* (issued 2003)
**From http://www1.od.nih.gov/osp/ospp/pdf/table_2.pdf

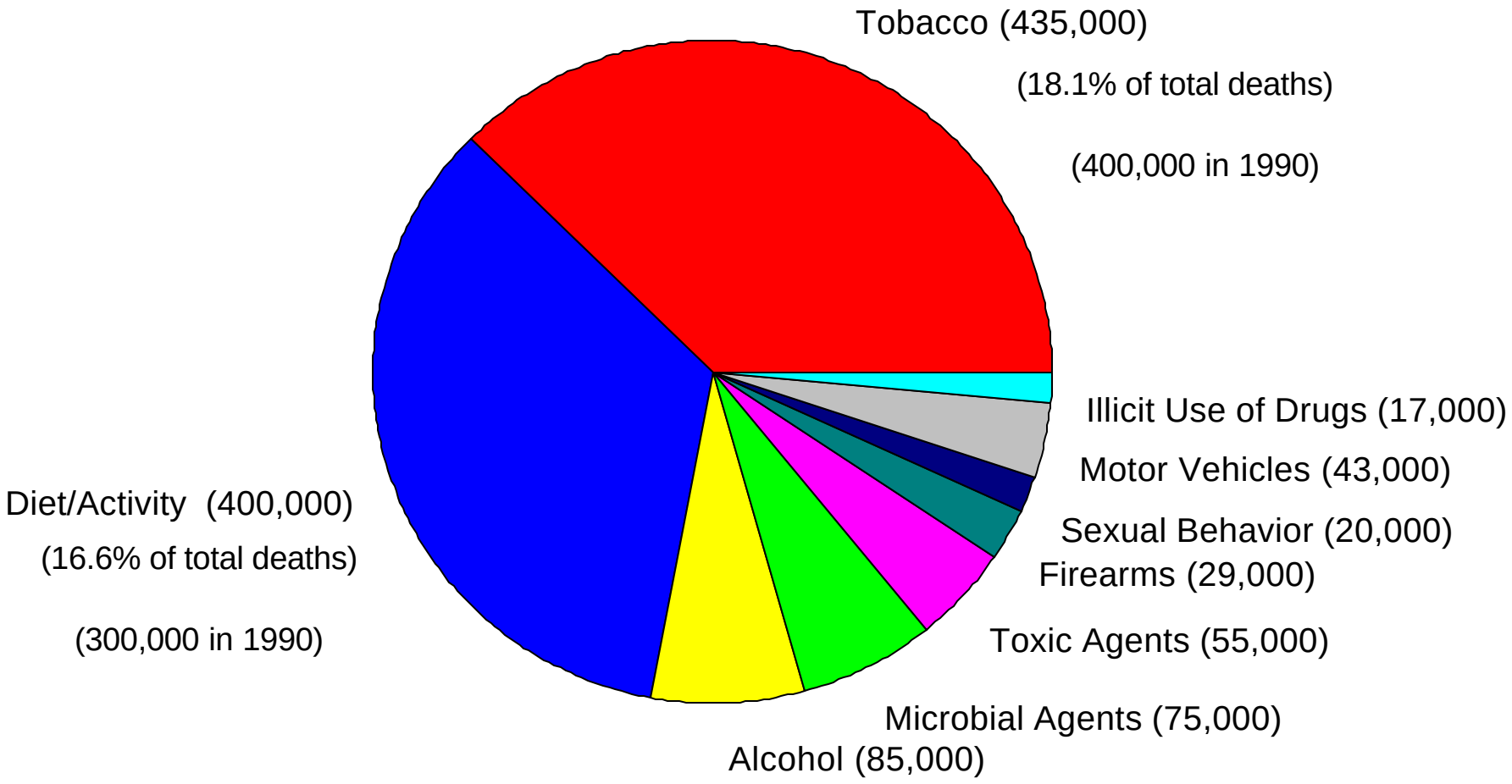
"Cigarette smoking is the chief avoidable cause of death in our society and the most important public health issue of our times."

C. Everett Koop, M.D.

Surgeon General of the United States, 1981 - 1989

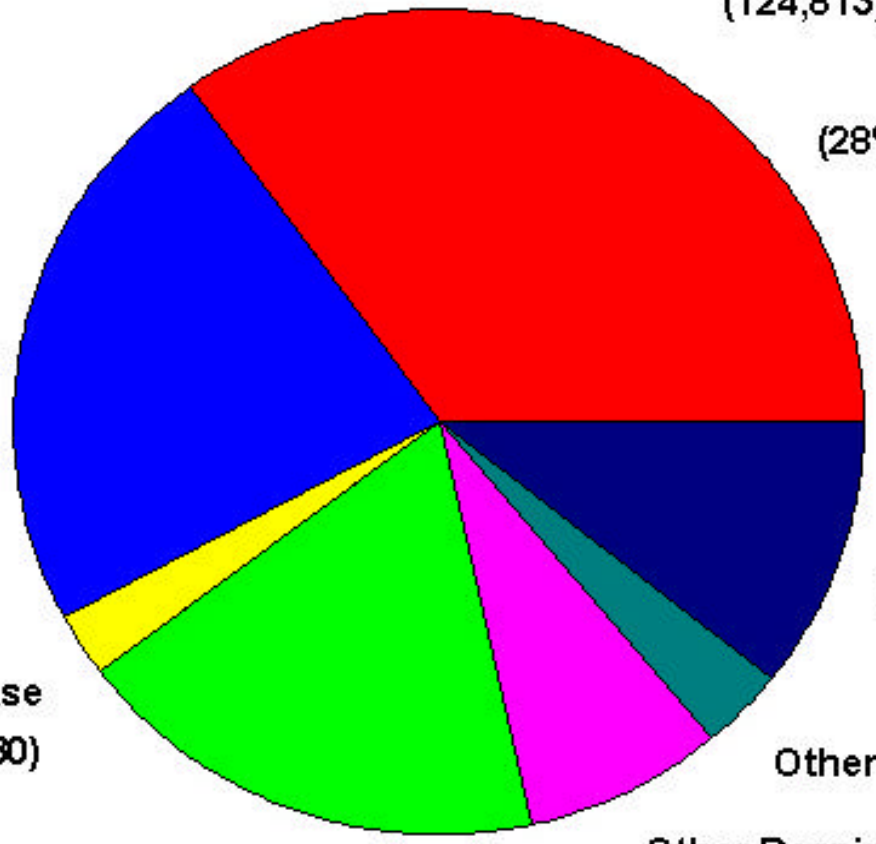
1,159,000 Preventable Causes of Death – 2000

(48.2% of 2,403,351 Total Deaths in 2000)



Mokdad AH et al. Actual Causes of death in the United States, 2000. JAMA. 2004;291:1238-1245

442,000 Annual Smoking-Related Deaths (1995-1999)



Infants - 1007 Deaths
Fires - 966 Deaths

MMWR, 2002, 51, 300-303

Focus on Lung Cancer

- Smoking causes 90% of lung cancer deaths
- Currently the leading cause of cancer death among women

Lung Cancer Rate in White Men and Cigarette Consumption

	1930	1948
Lung Cancer Rate	4.9 per 100,000	27.1 per 100,000
Per capita consumption	1500	3600

Number and Percentage of Cigarette Smoking-Attributable Conditions Among Current and Former Smokers, USA, 2000

Condition	Current Smokers	Former Smokers	Overall
Chronic Bronchitis	2,633,000 (49%)	1,872,000 (26%)	4,505,000 (35%)
Emphysema	1,273,000 (24%)	1,743,000 (24%)	3,016,000 (24%)
Heart Attack	719, 000 (13%)	1,755,000 (24%)	2,474,000 (19%)
All Cancer (except Lung)	358,000 (7%)	1,154,000 (16%)	1,512,000 (12%)
Stroke	384,000 (7%)	637,000 (9%)	1,021,000 (8%)
Lung Cancer	46,000 (1%)	138,000 (2%)	184,000 (1%)
TOTAL	5,412,000 (100%)	7,299,000 (100%)	**12,711,000** (100%)

Source: MMWR, 2003, 52, 842-844.

The Toll of Tobacco Addiction

- Tobacco causes premature death of almost half a million Americans each year
- 1/3 of all tobacco users in this country will die prematurely from tobacco dependence losing an average of 14 years of life
- $75.5 Billion spent annually on medical care for smoking-related conditions (8% of all expenditures for medical care)
- $81.9 Billion in lost productivity

Source: MMWR, 2002, 51, 300-303

Tobacco Addiction in Wisconsin:
CDC Behavioral Risk Factor Surveillance System 2002

- 23.3% of WI adults smoke
- 25.4% of males and 21.4% of females currently smoke
- 35.4% of 18-24 year-olds were current smokers
- Higher rates for:

African-Americans	28%
Hispanic	26%
Native Amer.*	43%
(White	23%)

*Based on 1997 NCHS data.

Tobacco Addiction in Wisconsin

- 923,000 adult smokers
- 88,000 high school smokers
- 15,900 kids under 18 will become daily smokers each year
- 7,800 smoking-related deaths each year
- $1.58 billion in annual smoking-related health care costs
- $1.41 billion in annual smoking-caused productivity losses

Source: Campaign for Tobacco-Free Kids

AMERICAN LUNG ASSOCIATION®
State of Tobacco Control: 2003

STATE REPORT CARD | STATE SUMMARY | STATE NARRATIVE | TAKE ACTION |

REPORT CARD

STATE OF TOBACCO CONTROL 2003
WISCONSIN

Grades:

Smokefree Air	F
Youth Access	D
Tobacco Prevention and Control Spending	F
Cigarette Taxes	C

Wisconsin FY 2004 Tobacco Prevention and Control Appropriations: **$11,141,265** (originally $23 million)

CDC Best Practices Range: **$31,158,000 - $82,381,000**

Wisconsin FY 2004 Tobacco Tax: **77 cents**

Health Benefits of Quitting Smoking

- After 1 year: Excess risk of coronary heart disease (CHD) is half that of a smoker
- After 5 years: Lung cancer death rate for the average former smoker decreases to almost half
- After 10 years: Lung cancer death rate is similar to that of nonsmokers
- After 15 years: Risk of CHD is that of a nonsmoker

Why is Quitting Smoking So Difficult?

- Nicotine is a psychoactive drug with rewarding effects
- Nicotine intake causes increases in brain dopamine, serotonin, and endogenous opioids
- Nicotine improves concentration and memory
- Nicotine has antidepressant and anxiolytic actions
- Regular users of tobacco develop tolerance and withdrawal
- Nicotine intake reduces hunger and helps prevent weight gain

Smoking Cessation

- 70-80% of smokers say they want to quit smoking
- About 35% try to quit each year
- 70% of smokers have made at least one unsuccessful quit attempt
- Smokers making unaided quit attempts have a long-term success rate of only about 5%
- Effective smoking cessation treatments are available and all tobacco users should be offered cessation treatment

Tobacco Use and Dependence

- Tobacco Dependence = Nicotine Dependence (but note that there is no Nicotine Abuse diagnosis in DSM-IV)
- Tobacco Dependence is a psychiatric disorder
- Not all smokers are dependent on nicotine
- About half of smokers who ever smoked daily for a month or more meet criteria for Nicotine Dependence (National Comorbidity Survey)
- DSM-based definition of “dependence” reflects compulsive use that results in functional impairment

Tobacco Use and Dependence

- Physiological factors
- Psychological factors
- Emotional factors
- Behavioral factors
- Social factors
- Economic factors

Nicotine From Cigarettes

- A cigarette is a sophisticated nicotine delivery device; delivers 1-2 mg of nicotine per cigarette
- Nicotine is rapidly absorbed in the oral mucosa and lungs; reaches brain in 7-10 seconds
- Nicotine can be stimulating or relaxing, depending on how a person smokes
- Tolerance develops with repeated smoking
- Nicotine withdrawal syndrome occurs with abstinence
- Smoking a cigarette causes the release of a variety of neurotransmitters

Nicotine

- Nicotine binds to nicotinic cholinergic receptors (nChRs)
- nChRs are found in the brain, the autonomic nervous system, and other parts of the body
- Nicotine mimics ACh, and competes for binding at nChRs
- Nicotine effects are mediated by neurotransmitter binding:

Acetylcholine	$\rightarrow$	improved behavior and memory
Dopamine	$\rightarrow$	pleasure
Norepinephrine	$\rightarrow$	pleasure, anorexia
β-endorphines	$\rightarrow$	reduction in anxiety and tension

Nicotine Withdrawal

- Half-life of nicotine is about 2 hours (metabolized in the liver)
- Nicotine levels drop between cigarettes which allows for re-sensitization of receptors and continued positive reinforcement
- Abstinence from nicotine leads to withdrawal syndrome which begins within 24 hours
- Peak symptoms last for days, weeks, or months
- Craving can last for months or years

Nicotine Withdrawal Symptoms

- Anger, hostility, frustration, irritability
- Anxiety, nervousness
- Craving for cigarettes
- Decreased heart rate
- Depression, drowsiness, fatigue
- GI disturbances (i.e., constipation)
- Headache
- Impaired concentration
- Increased appetite, weight gain
- Myalgia
- Insomnia

Tobacco Dependence and Mental Illness

- High rates of smoking are commonly observed in psychiatric patients
- Individuals with mental disorders typically smoke more cigarettes per day and they have greater difficulty quitting smoking
- Mentally ill smokers consume almost half of all cigarettes smoked in the U.S.:

  - about 28% of U.S. residents have a current mental disorder
  - mentally ill smokers consume about 44% of cigarettes sold

Smoking and Mental Illness: The National Comorbidity Study

- Population-based prevalence study
- Nationally representative sample
- 8098 respondents aged 15 to 54 years
- DSM-III-R diagnoses based on a structured psychiatric interview (CIDI)
- A subset of 4411 respondents answered questions about tobacco use

Source: JAMA. 2000;284:2606-2610

Smoking and Mental Illness: The National Comorbidity Study

- Current smoking defined as regular (but not necessarily daily) smoking in past 30 days
- Quit rate defined as the proportion of lifetime smokers (daily smoking for a month or more) who were not current smokers
- CIDI assessed 19 DSM-III-R disorders
- "Nonaffective psychosis" included schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, and atypical psychosis

Source: JAMA. 2000;284:2606-2610

Smoking and Mental Illness: The National Comorbidity Survey

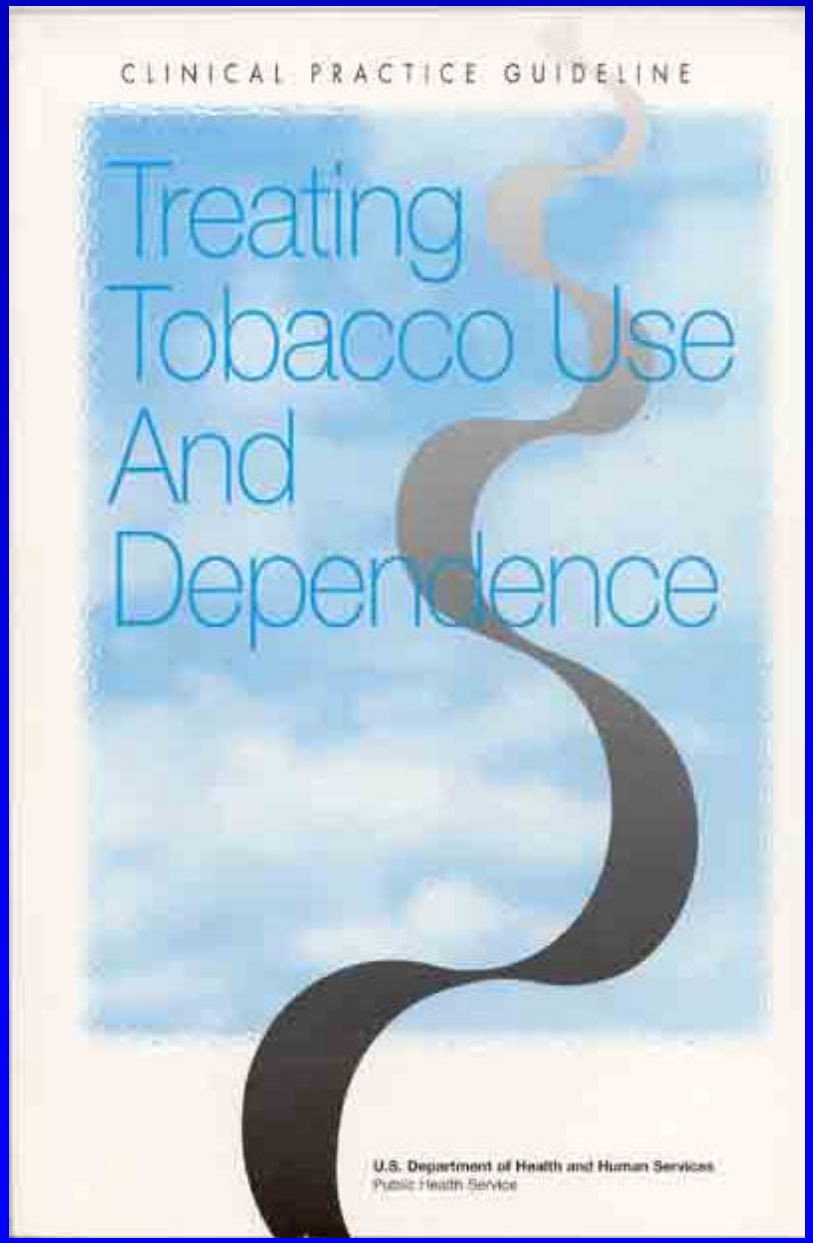
Past 30 Days	% Current Smoking	Quit Rate, %
• No Mental Illness	23	43
• Major Depression	45	26
• Nonaffective Psychosis	45	0
• Gen. Anxiety Disorder	55	29
• Alcohol Abuse or Dependence	56	17
• Bipolar Disorder	61	26
• Drug Abuse or Dependence	68	22

Source: JAMA. 2000;284:2606-2610

Smoking and Illicit Drugs: National Household Survey on Drug Abuse, 1997

Type of Drug	% Current Smoking	Quit Rate, %
• Marijuana	74	21
• Cocaine	84	13
• Hallucinogens	80	15
• Inhalants	70	21
• Crack cocaine	85	13
• Heroin	88	9

Source: Richter et al. (2002). A population-based study of cigarette smoking among Illicit drug users in the United States. Addiction, 97, 861-869.



U.S. Public Health Service Clinical Practice Guideline

Michael C. Fiore, MD, MPH
Panel Chair

Published June, 2000

Evidence-based

50 meta-analyses of
6000 articles (1975-1999)

Guideline Take-Home Messages

- Tobacco dependence is a **chronic disease** that often requires repeated interventions:
  - Long-term, chronic course
  - Periods of relapse and remission
  - Requires ongoing rather than acute care
- The disease is addiction to the nicotine in tobacco
- Every patient who uses tobacco should be offered treatment

Guideline Take-Home Messages

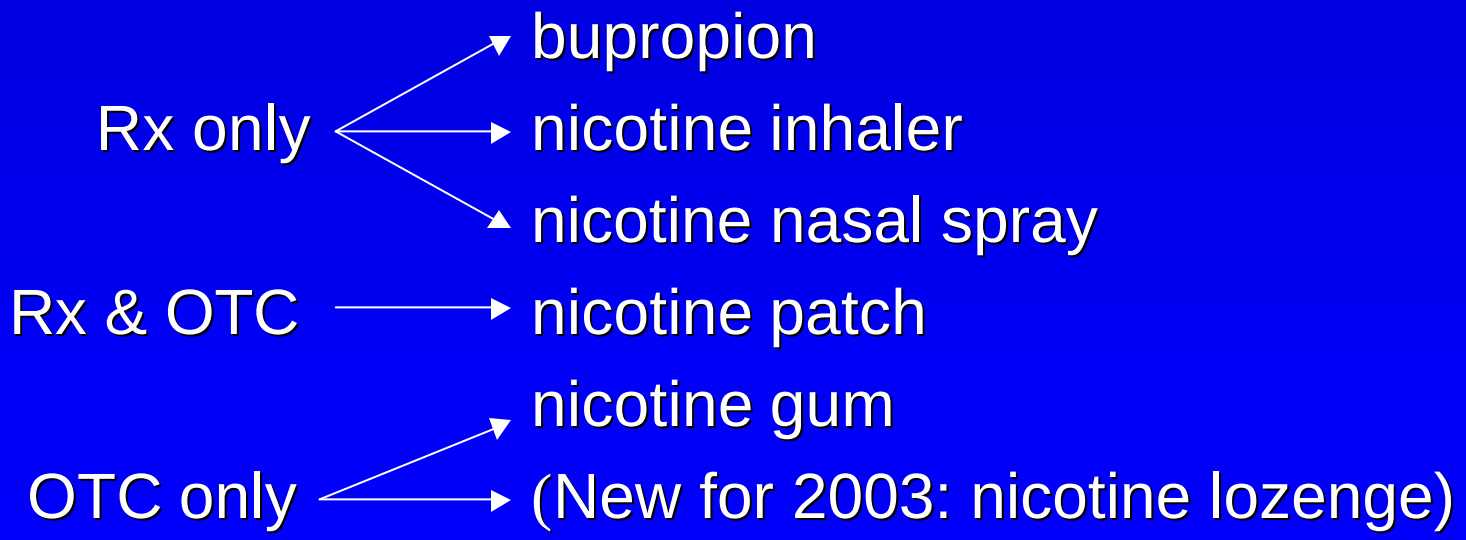
- Several types of treatment significantly increase success in quitting tobacco use:

  - nicotine replacement medications
  - Zyban (bupropion SR)
  - longer counseling sessions
  - more counseling sessions
  - problem-solving/skill-training counseling
  - combinations of the above

Guideline Take-Home Messages

- Pharmacotherapies are effective and should be used in every quit attempt, except in the presence of contraindications

- The first-line pharmacotherapy agents include:



Guideline Take-Home Messages

- Brief tobacco dependence treatment is effective, and every patient who uses tobacco should be offered at least brief treatment.

- For the patient willing to quit (5 A's):
  - Ask, Advise, Assess, Assist, Arrange

- For the patient unwilling to quit (5 R's):
  - Relevance, Risks, Rewards, Roadblocks, Repetition

The 5 A's: For Patients Willing To Quit

- ASK about tobacco use
- ADVISE to quit
- ASSESS willingness to make a quit attempt

  (If not willing to quit: 5 R's)
- ASSIST in quit attempt
- ARRANGE for follow-up

The 5 A's: ADVISE To Quit

- **Once tobacco use status has been identified and documented, advise all tobacco users to quit**
- **Even brief advice to quit results in greater quit rates**
- **Advice should be:**
  - -clear
  - -strong
  - -personalized

"As your health care provider, I must tell you that the most important thing you can do to improve your health is to stop smoking."

The 5 A's: ASSISTING the Motivated Patient - Overview -

- Help patient develop a quit plan
- Provide practical counseling
- Provide intra-treatment social support
- Help your patient obtain extra-treatment social support
- Recommend pharmacotherapy except in special circumstances
- Provide supplementary materials
- Arrange follow-up

The 5 A's: ASSISTING the Motivated Patient - Developing a Quit Plan -

- Set a quit date
- Review past quit attempts
- Encourage patient to tell family, friends, and others
- Anticipate challenges
- Remove tobacco products
- Avoid alcohol use
- Avoid exposure to tobacco or tobacco smoke

The 5 A's: ASSISTING the Motivated Patient - Counseling and Support -

- Problem-solving/skill training counseling
  - Encourage total abstinence from smoking
  - Review past quit experience
  - Anticipate triggers/challenges
  - Discuss risk factors: Alcohol use; other smokers; stress
- Provide supportive clinical environment
- Encourage extra-treatment support

The 5 A's: Assisting the Motivated Patient

Recommend the use of FDA-approved pharmacotherapy, except when contraindicated

- First-line medications: Bupropion SR, nicotine patch, nicotine gum, nicotine inhaler, nicotine nasal spray

- Second-line medications: Clonidine, nortriptyline (Not yet FDA-approved for smoking cessation)

- Also consider OTC nicotine lozenge

Who Should Receive Pharmacotherapy?

- All smokers trying to quit except for special circumstances

- Special considerations include:
  - medical contraindications
  - smoke < 10 cigarettes/day
  - pregnant/breastfeeding
  - adolescent smokers

Nicotine Replacement Therapy (NRT)

- Nicotine is the active ingredient
- Supplied as steady dose (patch) or self-administered (gum, inhaler, nasal spray, lozenge)
- Self-administered products should be used on scheduled basis initially before tapered to *ad lib* use and eventual discontinuation
- New nicotine lozenge available without a prescription

Nicotine Replacement Therapy (NRT)

- No evidence of increased cardiovascular risk with NRT
- Medical contraindications:
  - immediate myocardial infarction (< 2 weeks)
  - serious arrhythmia
  - serious or worsening angina pectoris
  - accelerated hypertension

Nicotine Gum

- Available without a prescription
- 2 mg vs 4 mg
- Chew and park
- Absorbed in a basic (not acidic) environment such as the oral mucosa
- Use enough pieces each day
- Available in 3 flavors: mint, orange, original
- Meta-analysis: OR=1.5 ([3] 5-month follow-up)
  estimated abstinence rate=24%

Nicotine Patch

- Available OTC and Rx (write “Legend Nicotine Patch”)
- A new patch is applied each morning
- Rotating placement site can reduce irritation
- Provides steady-state dose of nicotine
- Good patient acceptability because of ease of use
- Tapering of dose may be helpful for some individuals
- Meta-analysis: OR=1.9 ([3] 5-month follow-up)
  estimated abstinence rate=18%

Nicotine Inhaler

- Available by prescription only
- Nicotine is absorbed in the oral mucosa, so puffing of vapor into the mouth should be encouraged rather than inhaling of the vapor
- Frequent puffing is required
- Eating or drinking before and during administration should be avoided
- Meta-analysis: OR=2.5 ([3] 5-month follow-up)
  estimated abstinence rate=23%

Nicotine Nasal Spray

- Available by prescription only
- Patient should not sniff, swallow, or inhale the medication
- Initial dosing should be 1 to 2 doses per hour, increasing as needed
- Dosing should not exceed 40 per day
- Not as well accepted by patients
- Meta-analysis: OR=2.7 ([3] 5-month follow-up)
  estimated abstinence rate=31%

Nicotine Lozenge

- Available in 2 mg and 4 mg dosing without a prescription; light mint flavor
- Dose selection based on time to first cigarette
  - if > 30 minutes to 1st cig, use 2 mg
  - if ≤ 30 minutes to 1st cig, use 4 mg
- Avoid food and beverages for 15 minutes before and after using the lozenge
- Do not chew or swallow lozenge

Nicotine Lozenge - Dosing

Labeling: recommended length of use → 12 weeks

- First six weeks
  - One lozenge every 1-2 hours
  - Use at least 9 lozenges per day for first 6 weeks
  - Maximum of 20 per day
- Weeks 7-9
  - One lozenge every 2-4 hours
- Weeks 10-12
  - One lozenge every 4-8 hours

Nicotine Lozenge - Efficacy

Shiffman et al. *Arch Gen Psychiatry*, 2002;162:1267-1276

- Minimal behavioral support
- Continuous abstinence rates based on no smoking at the 2-week clinic visit and 4 weeks of sustained abstinence at the 6-week clinic visit (FDA definition)
- Abstinence confirmed by CO < 11 ppm
- Sample: mean age = 43; 57% female; 94% white
- Mean smoking rate: 22 cigs/day
- 63% had previously used pharmacotherapy

Nicotine Lozenge - Efficacy

	Low Dependence (2 mg lozenge)			High Dependence (4 mg lozenge)		
Time	Active	Placebo	OR	Active	Placebo	OR
12	34.4%	21.6%	1.97	35.3	14.0	3.42
24	24.2%	14.4%	1.96	23.6%	10.2%	2.76
52	17.9%	9.6%	2.14	14.9%	6.2%	2.69

Source: Shiffman et al. *Arch Gen Psychiatry*, 2002;162:1267-1276

Nicotine Lozenge

- Common side effects: nausea (12-15%)

  hiccups, coughing, heartburn, headache (5-8%)
- Smoker should consult physician if heart disease or hypertension is present or if the smoker is taking asthma medications or antidepressants
- Contains phenylalanine
- 12 week course of treatment = about 525 lozenges
- Lozenges cost about $40 for box of 72
- Total cost for 12 weeks = $290 or $3.50 per day

Combination Pharmacotherapy

Combination NRT

- Patch + gum or patch + nasal spray are more effective than a single NRT
- Encourage use in patients unable to quit using single agent
- Caution patients on risk of nicotine overdose
- Currently, not an FDA-approved treatment option

- Meta-analysis: OR=1.9 ([3] 5-month follow-up)
  estimated abstinence rate=29%

Bupropion SR

- Currently, the only non-nicotine medication approved by the FDA as an aid to smoking cessation treatment
- Available by prescription only
- Mechanism of action: presumably blocks neural reuptake of dopamine and/or norepinephrine
- Side effects: Insomnia, Dry mouth

Bupropion SR

- Contraindications
  - Seizure disorder
  - MAO inhibitor within previous 2 weeks
  - Hx of anorexia nervosa or bulimia
  - Current use of Wellbutrin
- Caution: There are several potential drug interactions between bupropion and psychiatric medications including antidepressants and antipsychotic medications

Bupropion SR

- Dosing:
  - start 1-2 weeks before quit date
  - 150 mg orally once daily x 3 day
  - 150 mg orally twice daily x 7-12 weeks
  - no taper necessary at end of treatment
- Maintenance - efficacious as maintenance medication for <6 months post-cessation
- Meta-analysis: OR=2.1 ([3] 5-month follow-up)
  estimated abstinence rate=31%

Relapse Prevention

- The majority of relapse occurs in the first two weeks
- Preventing Relapse
  - Congratulate success
  - Encourage continued abstinence
  - Discuss with your patient:
    - benefits of quitting
    - Barriers to success

"How has stopping tobacco use helped you?"

- If your patient has used tobacco, remind him or her that the relapse should be viewed as a learning experience
- Relapse is consistent with the chronic nature of tobacco dependence; not a sign of failure

The 5 R's: To Motivate Patients Unwilling To Quit

- **RELEVANCE**: Tailor advice and discussion to each patient
- **RISKS**: Outline risks of continued smoking
- **REWARDS**: Outline the benefits of quitting
- **ROADBLOCKS**: Identify barriers to quitting
- **REPETITION**: Reinforce the motivational message at every visit

Smoking Cessation in Substance Abusers

- Historically, substance abuse treatment programs have rarely or inconsistently encouraged smoking cessation
- Non-nicotine drugs of abuse often viewed as more important to address first
- Many residential treatment programs continue to allow smoking
- Also, some counselors have had the belief that smoking cessation concurrent with cessation of other drugs is too difficult and may lead to relapse

Smoking Cessation in Substance Abusers: Treatment Considerations

- Nicotine dependence in substance abusers may be more severe than dependence in non-abusers
- Substance-abusing smokers may need more intensive behavioral and pharmacotherapeutic interventions for smoking cessation
- Smokers with past but not current alcohol dependence have a similar rate of success compared with non-alcoholic smokers
- Smoking cessation does not increase alcohol relapse
- Continued smoking adversely affects treatment for marijuana dependence
- Smoking cessation is indicated for substance dependent persons already in recovery and may protect against relapse to the illicit drug of abuse

Wisconsin Tobacco Quit Line

1-877-270-STOP

toll free

Wisconsin Tobacco Quit Line
1-877-270-STOP

- Started in May, 2001; managed by UW-CTRI; funded by the State of Wisconsin
- Available: Monday-Thursday 7am-11pm

  Friday 7am-9pm

  Sat-Sun 8am-7pm
- Provides:
  - Free information for smokers and healthcare providers
  - Free telephone counseling sessions (up to 4 sessions)
  - Referrals to local cessation programs and services
  - Service for Spanish-speaking callers (1-877-2NO-FUME)
  - Service for hard-of-hearing (TTY 1-877-777-6534)

Wisconsin Tobacco Quit Line 1-877-270-STOP

- Cessation specialist conducts assessment and helps caller construct a personalized quit plan

Type of Caller	Intervention
Not ready to quit	One-call brief motivation intervention; Smoker encouraged to call back
Motivated quitter but no quit date	One-call intervention; Quit Kit is mailed; encouraged to set quit date
Motivated quitter with a quit date (next 30 days)	Initial comprehensive intervention up to 40 min.; Quit Kit mailed; 2 f/u calls
Motivated quitter with a quit date (next 30 days)	Initial comprehensive intervention up to 40 min.; Quit Kit mailed; 4 f/u calls

Wisconsin Tobacco Quit Line
1-877-270-STOP

Fax Referral Program:

- Healthcare providers can refer patients directly to the Quit Line by means of the Fax To Quit program
- With patient consent, Quit Line staff will make a call to the patient to initiate services after receiving FAX
- FAX to Quit Program information: 608-265-5617

Wisconsin Tobacco Quit Line
1-877-270-STOP

Independent Follow-up Survey

- Overall self-reported 6-month quit rate: 22%
- More intensive program quit rate: 26%
- Quit rates higher for males (28%) than for females (18%)
- Quit rates were higher for employed callers (31%) than for unemployed callers (12%)
- 79% reported using a combination of medication plus Quit Line counseling
- 55% reported using the more intensive program of 5 proactive calls from the Quit Line

Wisconsin Tobacco Quit Line
1-877-270-STOP

Free Patch Program for Uninsured or Underinsured Smokers

- Pilot program started in May, 2003, scheduled to end Dec, 2004; Partnering with 29 participating clinics serving under-served populations (Federally-funded Free Clinics and the Primary Health Care Network).
- Quit Line services and patches are provided to patients who would otherwise not be able to afford them.
- Each site implements the PHS Clinical Practice Guideline and the Fax to Quit program.
- 3000 courses of patch treatment available; 895 distributed so far

New Medications in Development

Rimonabant (Sanofi-Synthelabo)

- Selective CB1 endocannabinoid receptor antagonist
- Being tested for smoking cessation and weight loss
- Endocannabinoid system is involved in the appetite control system of the brain
- Rimonabant binds to CB1 receptors but does not appear to result in increased hunger
- U.S. efficacy study: 787 smokers
  - Ramonibant: 36.2% abstinent after 10 wks of treatment
  - Placebo: 20.6% abstinent

New Medications in Development

Varenicline (Pfizer)

- Partial nicotinic agonist
- Binds to nicotinic receptors but does not activate reward pathways as nicotine does
- Small efficacy study:
  - Varenicline: 48% abstinent after 7 wks of treatment
  - Burpropion SR: 33% abstinent
  - Placebo: 16% abstinent
- Phase 3 clinical trials currently underway

New Medications in Development

NicVAX (Nabi)

- Nicotine vaccine
- Vaccine generates nicotine-specific antibodies and elicits an immune response
- Nicotine binds to the antibodies and create a molecule that is too large to cross the blood-brain barrier, thus reducing the amount of nicotine that reaches the brain
- Phase 2 clinical trials currently underway

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